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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,392	03/28/2005	Mitsuru Takase	46243	6734

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EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,392	TAKASE ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-10 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-7, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by NOE Com, JP 1995-301882A.

NOE Com. discloses a process of purifying organic compounds comprising a dehydration step for decreasing the amount of water to a prescribed level or lower, wherein azeotropic dehydration is performed while adding a chloroform-containing solvent. The azeotropic dehydration is performed continuously and efficiently, by adding appropriate amount of alcohol and a non-polar solvent relative to the amount of water being removed by distillation. In preferred embodiment, the non-polar solvent is chloroform, dichloromethane or carbon tetrachloride. See ISR of PCT/JP03/12662.

Applicant should note that patentability of product-by-process claim is based on the product itself. Though, the claims are limited and defined by their process of making, the products are unpatentable if they are the same or obvious from the product of a prior art. *In re Thorpe,* 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray,*10 USPQ 2d 1922.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over NOE Com, JP 1995-301882A, alone or in view of Iwata et al., US 5,703,068.

Applicant claims a process for purifying an organic compound by dehydration: distillation of water from a polar organic solvent comprising the organic compound to a predetermined level of the water. The polar solvent is added repeatedly while water is removed. In preferred embodiments, the polar solvent has halogen, or it is a ether solution or ketone solvent, the dehydration is followed by crystallization of the organic compound, alcohol is added to the solvent to crystallize the organic compound, the solvent is product-by-process and the organic compound is a β-lactam compound.

Determination of the scope and content of the prior art (MPEP §2141.01

NOE Com. discloses a process of purifying organic compounds comprising a dehydration step for decreasing the amount of water to a prescribed level or lower, wherein azeotropic dehydration is performed while adding a chloroform-containing solvent. The azeotropic dehydration is performed continuously and efficiently, by adding appropriate amount of alcohol and a non-polar solvent relative to the amount of water being removed by distillation. In preferred embodiment, the non-polar solvent is chloroform, dichloromethane or carbon tetrachloride. See the ISR of the PCT/JP03/12662.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of NOE Com., is that applicant claims the solvent as product-by-process and the organic compound is a β-lactam compound. Also, applicant claims a crystallization step following the dehydration.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, Iwata et al., teach a process of purifying similar β-lactam compound (compound 9) by drying and then concentrating the organic solvent. See example 4 and Table 3. The β-lactam compound is further purified and crystallized. The process of making the solvent is not a limitation. Patentability of product-by-process claim is based on the product itself. Though, the claims are limited and defined by their process of making, the products are unpatentable if they are the same or obvious from the product of a prior art. *In re Thorpe,* 227 USPQ 964 (CAFC, 1985). See also *Ex parte Gray,*10 USPQ 2d 1922.

Therefore, the instant invention is prima facie obvious from the teachings of NOE Com. and Iwata et al. One of ordinary skill in the art would have known to apply the process of NOE Com. To purify a β-lactam compound and claim further crystallization step at the time the instant invention is made. The motivation is from the teaching of Iwata et al., of purifying β-lactam compound by drying and then concentrating the organic solvent, and further purification of the β-lactam compound and crystallizing it.

The instant process is not for making an organic compound as claimed by applicant. It is a purification step (recovery step) after the product is made. Under the US patent practice, such is not an invention. Recovery step per se is uninventive, it must be claimed with other significant steps. *Ex parte Deutschmann*, 114 USPQ 556 (1957).

IDS

Applicant does not submit the references cited in the IDS filed 3/28/05. US 5,703,068, is the US equivalent of WO 92/03444. A call was made to applicant's representative to file an English translation of the JP reference. Such must be filed in responding to this Office action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Thomas McKenzie, can be reached on (571) 272-0670. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1625

April 24, 2007